

Appl. No. : 10/053,014  
Filed : October 16, 2001

### REMARKS

#### Rejections Under 35 U.S.C. § 103

The Examiner has rejected Claims 26-41 under 35 U.S.C. § 103(a) as unpatentable over Perez, Jr. in view of Smith. The examiner asserts that switching the paddles of Perez does not place the claims outside the scope of obviousness to one of ordinary skill in the art. Applicants respectfully disagree.

#### The Examiner Has Not Established a *Prima Facie* Case of Obviousness

To establish a *prima facie* case of obviousness under 35 U.S.C. 103(a), three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Independent claims 26 and 38 are directed to a method of conducting an examination within the vaginal cavity, wherein, *inter alia*, a speculum is provided having a handle and a dilator, wherein the dilator consists of a shorter dilator member and a longer dilator member, and the shorter dilator member is positioned between the longer member and the handle.

As described in the background of the specification, prior art specula, such as the one disclosed in Perez, are difficult to use with patients who are being examined on a flat exam surface because the speculum interferes with the exam surface. These bed exams typically occur with gynecologic patients who are not being seen in a gynecologic office. For example, patients who have been hospitalized, are visiting emergency rooms, are pregnant, or are elderly may be seen on flat exam surfaces.

During an exam on a flat surface there is typically interference between the traditional speculum handle and the flat surface. Due to this interference there can be: (1) great difficulty in properly tilting the speculum into position for ideal presentation of the cervix; (2) increased manipulation of the speculum to avoid contact with the surface and/or patient's buttocks, causing the patient extreme discomfort, including, in some cases, pinching or compressing a section of

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the vaginal wall; and (3) touching of the speculum handle with non-sterile, inanimate objects such as the flat surface, or with the patient's skin, jeopardizing the speculum's sterility as well as that of the physician's gloved hands, leading to resterilization of the physician's hands or even ascending infection of the vaginal cavity.

To overcome this problem, physicians sometimes invert the speculum so that the handle points upwards instead of downwards. Unfortunately, if a physician inserts the speculum in an inverted position to solve this problem, the blade lengths are reversed and are set at improper angles. The upper blade is now longer than the lower blade, and is no longer capable of being adjusted angularly. Further, in an inverted position, the longer, now-upper blade makes it practically impossible for the physician to view the cervix which ends up pushed up behind the upper blade. Additionally, in this position the lever doesn't work properly in the inverted position and requires more manipulation by the physician, which can cause more pain for the patient.

The present claims are directed to a method that solves these problems by providing a speculum which is specifically designed to work in an inverted position. The claimed method includes use of a speculum with a shorter dilator member positioned between the long dilator member and the handle. Thus, when the speculum is positioned with the handle pointing upwards in an inverted position, the shorter dilator remains above the longer dilator, which is the proper position for a pelvic exam.

In light of the arguments presented above, Applicants respectfully submit that it would not be obvious to one of skill in the art at the time of the invention to "provide the Perez handle flipped with the shorter dilator on top," as asserted by the Examiner. Furthermore, there is no teaching or suggestion in the cited art to "provide the Perez handle flipped with the shorter dilator on top."

Indeed, Perez does not mention the problem in examining a patient on a flat exam surface. Because the problem was not recognized by Perez, there would be no suggestion or motivation, either in Perez or in the knowledge generally available to one of ordinary skill in the art, to modify Perez to provide a speculum with a shorter dilator member disposed between the handle and the longer dilator. Furthermore, since neither Perez nor Smith teach or suggest the particular problem to be solved - examining a gynecological patient on a flat exam table, there can be no motivation to combine Perez and Smith.

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In addition, the Perez reference does not teach or suggest all the claim limitations. The present claims refer to the use of a speculum with a shorter dilator member positioned between the longer member and the handle. Such a device is simply not taught in Perez nor is there a teaching or suggestion in Perez to modify the disclosed device to include the claimed dilator configuration.

For all of these reasons, the Examiner has not established that Applicants' claims are *prima facie* obvious in view of the teachings of Perez. Accordingly, Applicants respectfully request withdrawal of this rejection.

Applicants Have Rebutted Any Prima Facie Showing of Obviousness

Moreover, even if the Examiner has established a *prima facie* showing of obviousness, Applicants secondary considerations rebut any such showing.

As discussed above, to overcome longstanding problems with examining patients on a flat surface using conventional specula, such as the one disclosed by Perez, physicians invert the speculum so that the handle points upwards instead of downwards. Unfortunately, in this position, the blade lengths are reversed and are set at improper angles. The upper blade is now longer than the lower blade, and is no longer capable of being adjusted angularly. Further, in an inverted position, the longer, now-upper blade makes it practically impossible for the physician to view the cervix which ends up pushed up behind the upper blade. Additionally, in this position the lever doesn't work properly in the inverted position and requires more manipulation by the physician, which can cause more pain for the patient.

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Physicians have a long felt but unsolved need for a speculum that can be effectively used on a flat surface to view the vaginal cavity while also maintaining the sterilization of the procedure. The claimed methods solve this need by providing a speculum and method which is particularly advantageous for conducting an examination within the vaginal cavity of a patient

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who is laying on a flat surface, and cannot use stirrups. This secondary consideration weighs against a finding that the pending claims would be obvious in view of the teachings of Perez.

Moreover, the presently claimed invention has produced unexpected results. The presently claimed embodiments provide a more effective view of the cervix, minimize discomfort, and reduce the risk of infection to the patient. Each of these advantages is due to the unique configuration of the specula used in the claimed method.

Accordingly, Applicants maintains Claim 26 and 38 are patentable over Perez and Smith. As Claims 27-37 and 39-41 are dependent on independent Claims 26 and 38, Claims 27-37 and 39-41 are patentable for at least these reasons. Accordingly, Applicants respectfully request withdrawal of the obviousness rejections, and allowance of the pending claims.

#### CONCLUSION

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of this response, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

If the Examiner has any questions which may be answered by telephone, he is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: February 13, 2004

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